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10/590,831	10/11/2007	Sung Oh Chung	HANOL-13074	1454
72960 Casimir Jones, S	7590 02/08/201 S.C.	1	EXAMINER	
2275 DEMING	WAY, SUITE 310		LEAVITT, MARIA GOMEZ	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
	10/590,831	CHUNG ET AL.
Office Action Summary	Examiner	Art Unit
	MARIA LEAVITT	1633
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the	correspondence address
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	PATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be ting will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDON	DN. imely filed m the mailing date of this communication. ED (35 U.S.C. § 133).
Status		
 1) Responsive to communication(s) filed on <u>03 E</u> 2a) This action is FINAL. 2b) This 3) Since this application is in condition for alloward closed in accordance with the practice under E 	s action is non-final. Ince except for formal matters, pr	
Disposition of Claims		
4) ☑ Claim(s) 1-5 and 7-9 is/are pending in the app 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☑ Claim(s) 7-9 is/are rejected. 7) ☑ Claim(s) 1-5 is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o	wn from consideration.	
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9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomposed and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct of the oath or declaration is objected to by the Examine.	cepted or b) objected to by the drawing(s) be held in abeyance. Setion is required if the drawing(s) is older.	ee 37 CFR 1.85(a). bjected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Bureat * See the attached detailed Office action for a list	ts have been received. ts have been received in Applica prity documents have been receiv au (PCT Rule 17.2(a)).	tion No ved in this National Stage
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Profesoron's Patent Proving Povicy (PTO 948)	4) ☐ Interview Summar Paper No(s)/Mail [
Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Informal 6) Other:	

Detailed Action

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 and 7-9 are currently pending. Claims 1-5 have been amended and claims 7-9 have been added by Applicants' amendment filed on 12-03-2010. Claim 1 directed to an isolated polynucleotide comprising the nucleotide sequence of sequence ID NO: 1 is free of prior art.

Accordingly, new claims 7-9, drawn to a method of preparing L-carnitine comprising using a transformant comprising a recombinant vector comprising the polynucleotide of SEQ ID NO: 1 have been rejoined for examination by the Examiner.

Accordingly, claims 1-5 and 7-9 are currently under examination to which the following grounds of rejection are applicable.

Withdrawn objections/rejections in response to Applicants' arguments or amendments:

Claim Objections

In view of Applicant's amendment of claim 1, objection to claim 1 has been withdrawn.

35 USC 101-non-statutory subject matter

In view of Applicant's amendment of claim 1, to recite the phrase "an isolated polynucleotide" rejection to claims 1-5 under 35 USC §101 because the claimed invention is directed to non-statutory subject matter, has been withdrawn.

Claim Rejections - 35 USC § 112-Deposit Requirement

In view of Applicants' completed statement filed on 12/03/2010 that the plasmid identified by Accession Number KCCM- 10557 was deposited with the Korean Culture Center

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of Microorganisms on January 27, 2004 under the Budapest Treaty, rejection of claim 3 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement has been withdrawn.

Note that claim 5 does not require to be transformed with the vector Accession Number KCCM- 10557. Also note that Applicants have isolated a novel polynucleotide of SEQ ID NO: 1.

Claim Rejections - 35 U.S.C. § 102

In view of Applicant's amendment of claim 1, to recite an isolated polynucleotide as set forth in SEQ ID NO:1 encoding a γ -butyrobetaine hydroxylase which encompasses the full length of SEQ ID NO:1 with or without addition a nucleotides at either or both sides, rejection of claims 1, 2 and 4 under 35 U.S.C. §102(b) as being anticipated by Timberlake et al., (US Application NO: 12,336,504, Priority date September 23, 1999) has been withdrawn.

Timberlake et al., merely teaches isolated nucleic acid molecules having 28.9% sequence homology to the instant nucleotide sequence of SEQ ID NO: 1.

In view of Applicant's amendment of claim 1, to delete the recitation "a polynucleotide encoding a γ-butyrobetaine hydroxylase represented by SEQ ID NO: 2, rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by Galagan et al., (Nature 422:859-868 April, 2003; see SCORE Search Results Details for Application 10590831 and Search Result 20100622_105233_us-10-590-831-2.rup) has been withdrawn.

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Galagan et al., (Nature 422:859-868 April, 2003) discloses a nucleotide sequence encoding a predicted amino acid of 425 amino acids from Neurospora crassa having 100% homology to the a polynucleotide encoding the amino acid sequence of SEQ ID NO:2. Note that The amino acid sequence of SEQ ID NO2 of Galagan et al. is derived from an EMBL/GenBank/DDBJ whole genome shotgun (WGS) entry which is preliminary data.

Objections/Rejections maintained in response to Applicants' arguments or amendments:

Information Disclosure Statement

The information disclosure statement filed on January 05, 2010 remains objected as failing to comply with 37 C.F.R. § 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The following references have not been considered:

- a) Reference 2, JP S57-39791 (Date of Publication 1982-05-03), has not been considered as an English translation of the JP S57-39791 has not been provided.
- b) Reference 2, Galagan et al 2003, pp. 859-868, has not been considered as a legible copy of the publication has not been provided.
- c) Reference 4, Frederic et al., 1998, pp. 50-510, has not been considered as a legible copy of the publication has not been provided.
- d) Reference 5, Bach et al 1982, pp. 583-596, has not been considered as a legible copy of the publication has not been provided.
- e) Reference 6, Sandor et al., 1988, pp. 17-27, has not been considered as a legible copy of the publication has not been provided.

Response to Applicants' arguments as they relate to the IDS filed on January 05, 2010

At page 3 of the remarks filed on 10-03-2010, Applicants essentially argue that the references not considered were previously transmitted to the U.S. Patent Office via the PCT/KR2005/000532, of which this application claims the benefit of priority. Additionally, Applicants note that Reference 2, JP S57-39791 (date of publication 1982-05-03) has been considered by the Examiner as cited in the IDS.

Though the examiner agrees that the references not considered were previously transmitted to the U.S. Patent Office via the PCT/KR2005/000532, the mere citation of the reference is not deemed sufficient for examination of its disclosure. As previously stated in the office action of 07-07-2010, Applicants have not submitted an English translation of any portion of the cited documents. The office will consider a foreign document to the extent that an English abstract is provided. The office is not required to provide a machine translation of the abstract for the foreign documents but will acknowledge examination of the documents if an English translation of the Korean Abstracts is provided by Applicants.

Claim Rejections - 35 USC § 112- Second Paragraph

Claims 7-9 are newly rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a rejection necessitated by amendment of the claims in the response filed 12-03-2010.

Claim 7 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. While all of the technical details of a method need not to be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practice. The only disclosed step in claim 5 is using the γ -

butyrobetaine hydroxylase from a transformant. Is the claimed transformant cultivated? Are all transformants able to produce L-carnitine? Is the L-carnitine collected after being prepared? It is not apparent as to under what structural or functional parameters using the γ -butyrobetaine hydroxylase from a transformant is indicative or correlative to the preamble of the claims.

Claims 8 and 9 are indefinite insofar as they depend from claim 7.

New grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing L-carnitine comprising cultivating a Escherichia coli bacterium in a culture medium which contains γ -butyrobetaine as a substrate to cause accumulation of L-carnitine in the culture medium, and collecting L-carnitine from the culture medium, wherein the activity of a γ -butyrobetaine hydroxylase is induced as compared to a wild type strain, wherein the bacterium has been modified by transforming said bacterium with a recombinant plasmid comprising a gene encoding γ -butyrobetaine hydroxylase under the control of a potent promoter, wherein said gene encoding γ -butyrobetaine hydroxylase comprises a DNA selected from the group consisting of :

(a) a DNA which comprises the nucleotide sequence of SEQ ID NO: 1 and

(b) a DNA which encodes the protein comprising the amino acid sequence of SEQ ID NO:2,

does not reasonably provide enablement for other transformants, or other methods of preparing L-carnitine using a γ -butyrobetaine hydroxylase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While the written description and enablement requirements are separate and generally separable requirements, the instant application fails to meet either requirement for essentially the same reasons, as set forth below.

This is a new rejection necessitated by amendment of the claims in the response filed 12-03-2010.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404).

Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

Claim 7 is broadly drawn to a method of preparing L-carnitine using any transformant comprising a γ -butyrobetaine hydroxylase encoded by the nucleotide sequence of SEQ ID NO:1 or a nucleotide sequence encoding the amino acid of SEQ ID No. 2, wherein the method of preparing L-carnitine do not require any particular steps. Thus the claims broadly embrace methods for generating a genus of transformants able to grow on any substrate and to produce L-carnitine. This disclosure is not deemed to be descriptive of the complete structure of a representative number of transformants encompassed by the claims as one of skill in the art cannot envision all the transformants functionally able to produce L-carnitine based on the teachings in the specification. The specification does not teach other L-carnitine producing transformants in addition to bacterial strain E.coli transformed with the pT7-BBH2 plasmid able to grow on a culture medium comprising γ -butyrobetaine as a substrate.

The Court of Appeals for the Federal Circuit has recently held that a "written description

of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these (Enzo Biochem 63 USPQ2d 1609 (CAFC 2002)).

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. The specification discloses that E.coli strain BL21 (DE3) transformed with pT7-BBH2 comprising a gene encoding a γ -butyrobetaine hydroxylase from Neurospora crassa was cultured on a medium comprising γ -butyrobetaine. The accumulated L-carnitine concentration in the supernatant was 0.8 ug/ml relative to the non-transformed E.coli strain BL21 (DE3) (page 18, Table 18). However, the specification is silent about any other functional transformants able to produce L-carnitine in culture on a medium comprising γ -butyrobetaine as a substrate, let alone any substrate. Applicant merely provides one example wherein E.coli strain BL21 (DE3) transformed with pT7-BBH2 cultivated in a medium comprising γ -butyrobetaine as

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a substrate exhibits the claimed functionality.

The genus of microorganism, when given the broadest reasonable interpretation encompass genomes of bacterial, archaeal and eukaryotic (see search notes NCBI, Blast with microbial genomes and Eubacteria taxonomic groups in Fig 1, Cumming et al., FEMS Microbiology Letters 2002, p. 134). Complete genome of bacteria have been sequenced including many important human pathogens (e.g., Haemophilus influenza, Mycobacterium tuberculosis, M. leprae, Helicobacter pylori, Streptococcus pyogenes), including six distinct groups of E. coli with different pathogenic mechanisms (e.g., enteropathogenic E. coli, enterotoxigenic E coli, enterohemorrhagic E. coli, enteroinvasive E. coli, enteroaggregative E. coli and diffuse-aggregative E. coli (Medical Microbiology, Third edition, Mims et al., 2004, p. 280). In addition, transformants may also include yeast and fungus. The art teaches that genetically related transformant such as yeast comprising the same gene exhibit distinct phenotype. For example, in S. cerevisiae, the protein Cdc42p is essential for growth and is known to be involved in the establishment of polarity. S. cerevisiae yeast over-expressing dominant active or dominant negative alleles of this protein are lethal (Ziman et al., 1991 Mol Cell Biol. pp:3537-44.). In contrast to the S. cerevisiae cdc42 mutants, which are nonviable, Schizosaccharomyces pombe yeast over expressing the CDC42 mutant alleles are viable (Miller and Johnson, 1994 Mol Cell Biol. pp. 1075-83). Thus fundamental differences in morphology, cell cycle and growth may exist amongst different yeast species having the same gene. Further, genetically related yeast and fungi would exhibit a different phenotype following expression of the same gene. For example, DC42 in filamentous fungal species have a range of phenotypes that are very different from the phenotypes in yeasts: deletion of CDC42 or over-expression of

dominant active or dominant negative alleles did not cause lethality in a number of filamentous species. Dimorphic Penicillium marneffei possessing a CDC42 dominant negative allele are viable (Boyce et al. 2001 J Bacteriol, pp. 3447-57). Over expression of the dominant negative allele in C. purpurea stimulated branching and sporulation, while over expression of dominant active allele abolished sporulation. C. purpurea cdc42 deletion mutants were viable but nonpathogenic. Over expression of dominant active CDC42 allele had little effect on vegetative growth but affected appressoria formation and reduced spore germination in Colletotrichum trifolii (Chen et al., 2006 Eukaryot Cell. Pp.155-66). Over expression of dominant active and dominant negative alleles of CDC42 eliminated sporulation in Aspergillus nidulans but not in P. marneffei (Boyce et al., 2001; Momany, 2002 Curr Opin Microbiol. pp. 580-5). Applicant provides only one example of E.coli strain transformed with the pT7-BBH2 plasmid encoding the γ-butyrobetaine hydroxylase of SEQ ID NO:2 from Neurospora crassa able to produce Lcarnitine. The specification does not provide any disclosure as to what would have been the required structure for the claimed genus of nucleotide sequences encoding the amino acid sequence of SEQ ID NO:2 to be functional on other transformants.

Next then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g., amino acid sequence), specific features and functional attributes (e.g., cycle of replication) that would distinguish different members of the claimed genus. However, the instant specification or the prior art does not describe sufficient species for the structure of claimed genus genes, i.e., the nucleotide sequence of SEQ ID NO:1 or a nucleotide sequence encoding the amino acid of SEQ ID No. 2 sufficiently for one skilled in the art to use for generation of any transformant so as to exhibit γ -

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butyrobetaine hydroxylase activity. In the instant case, no other characteristic in addition to the functional discussed above are disclosed. Such functional characteristics, however, do not allow one of skill in the art to distinguish the different members of the genera form each other.

Applicant's attention is directed to In re Shokal, 113 USPQ 283 (CCPA 1957), wherein it is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 CCPA (Patents) 1309, 97 F2d 623, 38 USPQ 189; In re Wahlforss, 28 CCPA (Patents) 867, 117 F2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicant is in possession of methods for generating a genus of transformants comprising a vector comprising the nucleotide sequence of SEQ ID NO:1 or a nucleotide sequence encoding the amino acid of SEQ ID No. 2 able to grow on any substrate so as to produce L-carnitine from any substrate, at the time the application was filed.

Thus it is concluded that the written description requirement is not satisfied for the claimed genus. Further, the breadth of the claimed invention is broader than indicated as allowable subject matter.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This is a new rejection necessitated by amendment of the claims in the response filed 12-03-2010.

Claim 7 is incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. While all of the technical details of a method need not to be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practice. The only disclosed step in claim 5 is using the γ -butyrobetaine hydroxylase from a transformant. It is not apparent as to under what structural or functional parameters is using the γ -butyrobetaine hydroxylase from a transformant is indicative or correlative to the preamble of the claims.

Claim 9 is vague and indefinite in that the metes and bounds of the phrase "wherein the recombinant vector has accession number KCCM-10557" are unclear. Though applicants have filed a deposit for the plasmid identified by Accession Number KCCM- 10557 with the Korean Culture Center of Microorganisms on January 27, 2004 under the Budapest Treaty, a look at page 15, lines 12-17 of the specification as filed appears to indicate that the deposit assigned accession number KCCM-10557 was made for the E. coli DH5alpha CJ2004. As such, the metes and bounds of the claim cannot be determined.

Claim 8 is indefinite insofar as they depend from claim 7.

Claim Objection

Claim 3 is objected to because applicants have filed a deposit for the plasmid identified by Accession Number KCCM- 10557 with the Korean Culture Center of Microorganisms on January 27, 2004 under the Budapest Treaty. However, a look at page 15, lines 12-17 of the specification as filed appears to indicate that the deposit assigned accession number KCCM- 10557 was made for the E. coli DH5alpha CJ2004.

Appropriate correction is requested.

Claim 1 and dependent claims 2 4 and 5 are objected to because of the recitation "an isolated polynucleotide as set forth in SEQ ID NO:1" in claim 1. As a polynucleotide sequence encodes a polypeptide or protein, claim 1 should be amended to recite "an isolated polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO: 1" or "an isolated polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1".

Appropriate correction is requested.

Conclusion

Claims 7-9 are rejected.

Claim 1-5 are objected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Maria Leavitt/

Maria Leavitt Primary Examiner, Art Unit 1633